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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)



Applicant's or agent's file reference J.	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EG2003/000009	International filing date (day/month/year) 22.11.2003	Priority date (day/month/year) 24.09.2003
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant LOTFY, Wael Mohamed Nabil		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 16.04.2005	Date of completion of this report 29.12.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Hedels, B Telephone No. +49 89 2399-2329 

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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EG2003/000009**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1, 2 as originally filed

Claims, Numbers

7-22 as amended (together with any statement) under Art. 19 PCT
1 filed with telefax on 27.08.2005

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 2-6
☐ the drawings, sheets:

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5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7-22

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 7-22 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1
Industrial applicability (IA)	Yes: Claims	1
	No: Claims	

2. Citations and explanations

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**INTERNATIONAL PRELIMINARY
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International application No. PCT/EG2003/000009

Concerning section I.5.

It was not disclosed in the application as originally filed whether the inflatable lining is detachable or not detachable to the stent. Hence, the incorporation of the feature into claim 1 that the inflatable lining is a "non detachable" lining offends against Art. 34(2)(b).

Concerning section III.

The features specified in claims 7-22 were not disclosed in the application as originally filed. There are no passages in the application as originally filed disclosing the features defined in claims 7-22. Hence, these claims offend against Art. 19(2) PCT.

Concerning section V.

The above objection in section I.5 notwithstanding, the subject-matter of claim 1 lacks novelty in terms of Art. 33(2) PCT.

Claim 1 contains both alternatives which were originally claimed in two separate independent claims, namely the combination of a fixed lining and a stent was claimed in original claim 2 and the combination of an inflatable lining and a stent was claimed in original claim 1.

- As regards the combination of the inflatable lining and the stent, the lack of novelty objection is maintained.

WO-A-01/52769 (D1) (see Figs. 3 and 4 and the description, page 7, line 15 to page 8, line 10) discloses a stent 13 and an inflatable lining 24. Although the balloon is removed in D1 once the stent is positioned inside the blood vessel, the balloon could also be used to control the blood flow. Since the structural features claimed in claim 1 (namely the combination of an inflatable lining which can be of any shape and material and a stent which can also be of any shape and material) are disclosed in D1 and this combination could be used for controlling the blood flow inside the blood vessel, the subject-matter of claim 1 does not meet the requirement of novelty (Art. 33(2) PCT) (see the PCT-Guidelines for examination, Chapter 12.05).

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The feature that the inflatable lining is an integral part of the stent and is permanently associated with the stent was not originally disclosed (see item 1. above). It can therefore not be taken to distinguish the invention from the prior art.

- As regards the combination of the fixed lining and the stent, the lack of novelty objection is also maintained.

US-A-6 293 968 (D2) discloses a stent 50 and a graft 132 fixed to the stent (see Fig. 5). By means of the lining 132 the flow through the stent is controlled in that less blood can flow through the stent than without the lining and the risk of aneurysm rupturing is reduced.

Although it is true that the lining in D2 is first of all for preventing blood flow from the lumen of the stent to the outside against the wall of the vessel (intraluminal to extraluminal), the lining in D2 has nevertheless a definite wall thickness which narrows the inside diameter of the stent and thus reduces the intraluminal blood flow through the stent.

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Claims:

1. The addition of fixed and/or inflatable and/or compressible and/or controllable non detachable lining to stents (medical or non medical) to control the flow of fluids or gases through:

a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use.

b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal ...etc.

c. This includes all shapes and materials of linings used for the same purpose including but not limited to Gortex, Teflon, PTFE.

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